23234. Adulteration and misbranding of Capsules Elixir Luminol, and misbranding of Capsules Sedative, Capsules Amidonal and Capsules Cincopyrans. U. S. v. Philadelphia Capsule Co., Inc., and Joseph McManus. Plea of nolo contendere. Judgment of guilty. Fine, \$150. (F. & D. no. 31342. Sample nos. 38157-A, 38158-A, 38168-A, 38169-A.)

Analyses of the products covered by this case showed that they contained certain drugs in amounts differing from the amounts declared on the label. The label of the Capsules Sedative bore unwarranted curative and therapeutic claims and the label of the Elixir Luminol failed to bear a statement of the quantity or proportion of alcohol contained therein—approximately 16.7 percent

by volume.

On June 6, 1934, the United States attorney for the Eastern District of Pennsylvania, acting upon a report by the Secretary of Agriculture, filed in the district court an information against the Philadelphia Capsule Co., Inc., a corporation, and Joseph McManus, of Philadelphia, Pa., alleging shipment by said defendants in violation of the Food and Drugs Act, as amended, on or about April 18 and April 22, 1933, from the State of Pennsylvania into the State of New Jersey, of a quantity of Capsules Elixir Luminol which were adulterated and misbranded, and of quantities of Capsules Sedative, Capsules Amidonal, and Capsules Cincopyrans which were misbranded. The articles were labeled in part: "Capsules Elixir Luminol * * * Each Fl. Oz. Represents Phenobarbital 8 Grs."; or "Capsules Sedative Represents Ammonium Bromide 2½ Grs."; or "Amidonal Represents * * Amidopyrine 2½ Grs."; or "Cincopyrans Represents * * Amidopyrine 1½ Grs.", "Capsulated by The Philadelphia Capsule Co., Inc., Philadelphia, Pa."

The information charged adulteration of the Elixir Luminol in that its strength and purity fell below the professed standard and quality under which it was sold, since each fluid ounce was represented to contain 8 grains of phenobarbital, whereas each fluid ounce contained less than 8 grains, namely, not

more than 6.44 grains of phenobarbital.

Misbranding of all products was alleged in that the statement, "Each fl. Oz. represents Phenobarbital 8 grs.", with respect to the Elixir Luminol, was false and misleading, since each fluid ounce of the article contained less than 8 grains of phenobarbital; in that the statement, "Capsules Sedative represents Ammonium Bromide 21/2 gr." with respect to the Capsules Sedative, was false and misleading, since each capsule contained more than 21/2 grains, namely, not less than 3.1 grains of ammonium bromide; in that the statement, "Amidopyrine Grs. 21/2", with respect to the Amidonal capsules, was false and misleading, since each of said capsules contained more than 21/2 grains, namely, not less than 2.807 grains of amidopyrine; and in that the statement, "Amidopyrine Grs. 11/2", with respect to the Cincopyrans capsules, was false and misleading, since each of said capsules contained more than 11/2 grains, namely, not less than 1.87 grains of amidopyrine. Misbranding of the Capsules Sedative was alleged for the further reason that certain statements on the bottle label, falsely and fraudulently represented that the article was effective as a treatment for nervousness and insomnia due to overwork or worry, sexual excess, epilepsy, or delirium. Misbranding of the Elixir Luminol was alleged for the further reason that it contained alcohol and the label on the package failed to bear a statement of the quantity or proportion of alcohol contained in the article.

On September 21, 1934, a plea of nolo contendere was entered and the court

found the defendants guilty and imposed a fine of \$150.

M. L. Wilson, Acting Secretary of Agriculture.

23235. Adulteration and misbranding of Madame Heil Ammon's Get Well, Eat Well, Gall Stone Remedy, Antiseptic Wash, and Stay Young; and misbranding of Madame Heil Ammon's Oil Gall Stone Remedy. U. S. v. Catherine Heil Ammon (Home Remedy Co.). Plea of guilty. Fine, \$100 and costs. (F. & D. no. 31364. Sample nos. 2978-A, 10862-A to 10865-A, incl. 33787-A, 33788-A, 33793-A, 33794-A, 34041-A, 34042-A.)

This case was based on interstate shipments of certain "Madame Heil Ammon's" remedies, the labeling of which contained unwarranted curative and therapeutic claims. The Get Well, Eat Well, Gall Stone Remedy, and Stay Young contained less alcohol than declared on the labels. Bacteriological tests of the Antiseptic Wash showed that it was not an antiseptic when used as directed.

On August 14, 1934, the United States attorney for the Western District of Pennsylvania, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Catherine Heil Ammon, trading as the Home Remedy Co., Pittsburgh, Pa., alleging shipment by said defendant, in violation of the Food and Drugs Act as amended, on or about January 3, January 4, January 6, and January 17, 1933, from the State of Pennsylvania into the States of Minnesota, New York, Illinois, and Missouri of quantities of Madame Heil Ammon's Get Well, Eat Well, Gall Stone Remedy, Antiseptic Wash, and Stay Young, which were adulterated and misbranded, and of quantities of Madame Heil Ammon's Oil Gall Stone Remedy which was misbranded. The articles were labeled in part: "Madame Heil Ammon's Get Well [or "Eat Well", "Gall Stone Remedy", Antiseptic Wash", "Stay Young", or "Oil Gall Stone Remedy"] * * Prepared by the Home Remedy Co. * * * Pittsburgh, Pa."

Analyses of samples of the articles showed that the Get Well, Eat Well, Stay Young and one sample of the Gall Stone Remedy consisted essentially of extracts of plant drugs, alcohol (7.8 percent, 10.7 percent, 8.9 percent, and 8.8 percent, respectively), and water; that one sample of the Gall Stone Remedy consisted essentially of extracts of plant drugs, alcohol (8.5 percent by volume), and water and was accompanied by a small envelop containing Epsom salts; that one sample of the Gall Stone Remedy consisted essentially of extracts of plant drugs, including podophyllum, alcohol (8.6 percent by volume), and water, and was accompanied by a small envelop containing Epsom salts; that the two samples of the Oil Gall Stone Remedy consisted essentially of an oil having the odor of olive oil, and extracts of plant drugs including podophyllum; and that the sample of Antiseptic Wash consisted essentially of extracts of plant drugs and water, and was accompanied by a box of suppositories consisting essentially of boric acid, ammonium alum, fats, and waxes. Tests of the Antiseptic Wash showed that it was not an antiseptic wash when used as directed.

The information charged adulteration of the Get Well, Eat Well, Gall Stone Remedy, and Stay Young, in that they fell below the professed standard and quality under which they were sold since they were represented to contain 15 percent of alcohol, whereas they contained less than 15 percent of alcohol. Adulteration of the Antiseptic Wash was alleged for the reason that its strength and purity fell below the professed standard and quality under which it was sold in that it was represented to be an antiseptic wash, when used as directed:

whereas it was not an antiseptic wash when used as directed.

Misbranding of the Get Well, Eat Well, Gall Stone Remedy and Stay Young was alleged for the reason that the statements on the labels, "15 Per Cent Alcohol" or "15% Alcohol", were false and misleading, since they contained less than 15 percent of alcohol; and for the further reason that they contained alcohol and the labels failed to bear a statement of the quantity or proportion of alcohol contained therein. Misbranding of the Antiseptic Wash was alleged for the reason that the statement, "Antiseptic Wash", borne on the bottle label, was false and misleading, since the article was not an antiseptic when used as directed. Misbranding was alleged with respect to all products for the reason that certain statements in the labeling, falsely and fraudulently represented that they were effective (Get Well, bottle and carton) as a treatment, remedy, and cure for kidney and bladder ailments; effective to clean, heal, and strengthen the urinary organs, to remove gravel and stone and to strengthen the bladder so that urine can be retained and prevent getting up at night; effective to relieve lumbago, backache. sore and stiff feeling in the morning especially across the loins, dizzy spells, nervousness, rheumatism, sour stomach, tired and languid feeling, and many other ills due to uric acid in the system; effective as a never failing kidney and bladder remedy; effective to insure the urine to flow freely and to dissolve gravel and stone; (Get Well, circular) as a treatment, remedy, and cure for nervousness, rheumatism, sleeplessness, nervous breakdown, sour stomach, loss of appetite, headache, soreness and stiffness on arising with pain across the loins, lack of ambition, anemia, fatigue, getting up at night, shortness of breath, heart trouble, dropsy, swelling of limbs, suppression of urine, acid condition of the system, and other complications due to uric acid; effective as a relief for heart trouble and rheumatism caused by uric acid; effective to clean the bowels; effective to remove decayed matter that will remain in the bowels for months and sometimes for years; effective as a treatment, remedy, and cure for fits, convulsions, hysteria, asthma, bronchitis, Bright's disease, sugar diabetes, dizzy spells, auto-intoxication, and numerous other ailments caused by uric acid; effective to relieve prostate gland trouble;

effective as a treatment for pregnant women; and effective as a treatment, remedy, and cure for prolapsus, leaking kidney, inflammation of the bladder, complication of diseases, inflammation of the kidneys, and swollen ankles; (Eat Well, bottle, carton, circulars, and booklet) as a treatment, remedy, and cure for stomach and liver troubles; effective to give tone to the stomach and to act upon the liver by increasing the flow of bile and to promote its ejection; effective to increase and improve the secretion and movement of the stomach, and as a relief of indigestion, dyspepsia, and loss of appetite; effective to promote health and to relieve pain, anguish, and agony; effective as a treatment, remedy, and cure for indigestion; and effective as a stomach and liver tonic; (Oil Gall Stone Remedy, bottle and carton) as a remedy for gall stones; (Oil Gall Stone Remedy, circulars and booklet) as effective as a treatment in all cases of gall stones or any trouble in the gall bladder, intestinal tract, and appendix; and effective as a treatment of many complications such as soreness or heavy feeling at the pit of the stomach, sometimes extending to right or left side under the short ribs, pain in back extending up under the shoulder blades, stomach disorder, distention after eating, loss of appetite, energy and strength, debilitation, gas, belching, headache, dyspepsia, indigestion, constipation, biliousness, colic, irritability, nervousness, depression, melancholia, autointoxication, malassimilation, malnutrition or wasting of the flesh; effective as a treatment for stomach trouble due to liver and gall stone disturbance; effective to remove gall stones; and effective as a treatment, remedy, and cure for sick headache, weak and run-down condition and bilious attacks; effective as a cure for gall stones, stomach, liver and bowel disorders; effective to clean and strengthen the gall bladder and help to expel gall stones and other poisonous matter located in the gall bladder, intestinal tract, and appendix; and effective as a treatment for hepatic colic, acute indigestion, intense pain, vomiting, cold and clammy skin, and great prostration due to gall stones; effective to relieve every uncomplicated case of gall stones and appendicitis; effective to promote health and to relieve pain, anguish, and agony; and effective as a preventive of kidney trouble, heart trouble, diabetes, and cancer; (Gall Stone Remedy, carton and bottle) as a remedy for the relief of gall stones, stomach, liver and bowel disorders; effective to clean and strengthen the liver, stomach and bowels and increase the flow of bile; effective as a relief of hepatic colic, soreness at the pit of the stomach extending around the right side, vomiting, distention after eating, loss of appetite, strength and energy, heavy feeling at pit of stomach, and pains at either the right or left side under the short ribs often extending upwards to the shoulder blades; (Gall Stone Remedy, circulars and booklet) as a treatment for stomach disorder, distention after eating, loss of appetite, energy and strength, debilitation, gas, belching, headache, dyspepsia, indigestion, constipation, biliousness, colic, irritability, nervousness, depression, melancholia, auto-intoxication, malassimilation, malnutrition, or wasting of the flesh, due to gall stones; effective as a treatment for stomach trouble due to liver and gall stone disturbance; effective to remove gall stones; effective as a treatment, remedy, and cure for sick headache, weak and run-down condition, bilious attacks and indigestion; effective to promote health and to relieve pain, anguish, and agony; effective as a cure for gall stones, stomach, liver and bowel disorders; effective to clean and strengthen the gall bladder, and help expel gall stones and other poisonous matter located in the gall bladder, intestinal tract, and the appendix; effective as a treatment for hepatic colic, acute indigestion, intense pain, vomiting, cold and clammy skin, and great prostration due to gall stones; effective to relieve every uncomplicated case of gall stones and appendicitis; effective as a treatment for all stomach trouble due to gall bladder disturbance; effective as a treatment for kidney trouble, heart trouble, diabetes, and cancer due to neglected gall bladder conditions; and effective as a treatment for congested gall bladder caused by an infection or catarrhal condition; (Antiseptic Wash, bottle, circular, and folder) as a healing and strengthening power in female troubles; effective to draw the inflammation from the generative organs; effective when used in connection with Stay Young to insure good health, strength, and vitality regardless of the length of previous sickness; effective as a treatment, remedy, and cure for all female weakness and disorders; effective to strengthen and restore health to the generative organs and as a positive relief from ulceration, inflammation, anteversion, retroversion and prolapsus, leucorrhea, ovarian troubles, difficult menstruation, cysts and fibroid tumors, and congestion and falling of the womb; and effective when used in connection with Stay Young X Medicine as a treatment, remedy, and cure for profuse menstruation

or flooding spells, symptoms of female weakness, such as nervousness, headache, backache, pains in the lower part of the abdomen, sometimes with bearing down pain, down and out feeling, low spirits, a tired languid feeling, no ambition, bladder trouble, caused by enlarged womb pressing against the bladder, and leucorrhea; (Stay Young, bottle and carton) as effective, when used by young girls, to retain youth and as a treatment, remedy, and cure for all female weaknesses and disorders, to strengthen and restore to good health the generative organs, and as a positive relief for ulceration, inflammation, anteversion, retroversion, and prolapsus, leucorrhea, ovarian troubles, difficult menstruation, cysts and fibroid tumors, congestion and falling of the womb: effective when used in connection with Antiseptic Wash and Suppository by women, to insure youth, and as a treatment, remedy and cure for all female weaknesses and disorders, to strengthen and restore to good health the generative organs and as a positive relief for ulceration, inflammation, anteversion, retroversion and prolapsus, leucorrhea, ovarian troubles, difficult menstruation, cysts and fibroid tumers, and congestion and falling of the womb; and effective when used in connection with Stay Young X as a treatment, remedy, and cure for profuse menstruation.

On October 29, 1934, the defendant entered a plea of guilty and the court imposed a fine of \$100 and costs.

M. L. Wilson, Acting Secretary of Agriculture.

23236. Adulteration and misbranding of syrup of hypophosphites compound, elixir iron pyrophosphites, quinine and strychnine, and elixir triple bromides; and misbranding of fluid extract of hydrastis aqueous. U. S. v. P. H. Mallen Co. Plea of nolo contendere. Fine, \$200 and costs. (F. & D. no. 31441. Sample nos. 3663-A, 3664-A, 3665-A, 3667-A.)

This case was based on an interstate shipment of certain drug preparations recognized in the National Formulary, which fell below the standard laid down in that authority, and which contained certain therapeutic agents in amounts differing from those declared on the labels. The case also covered a product labeled to convey the impression that it was fluidextract of hydrastis, a product recognized in the United States Pharmacopoeia, but which consisted of a weak alcoholic solution of hydrastis, containing materially less of the alkaloids of hydrastis and alcohol than the pharmacopoeial product. The labeling of all products contained unwarranted curative and therapeutic claims.

On May 24, 1934, the United States attorney for the Northern District of Illinois, acting upon a report by the Secretary of Agriculture, filed in the district court an information against the P. H. Mallen Co., a corporation, Chicago, Ill., alleging shipment by said company, in violation of the Food and Drugs Act, as amended, on or about July 21, 1932, from the State of Illinois into the State of Michigan, of quantities of pharmaceuticals which were misbranded and portions of which were also adulterated. The articles were labeled: "Fluid Hydrastis Fluid Extract Hydrastis Can. Aqueous Golden Seal"; "Syrup Hypophosphites Compound (Hematic) Each Fluid Ounce Contains * * * Quinine Hypophosphites 1 grain Strychnine Hypophosphites Is Grain"; "Elixir Iron Pyrophosphites, Quinine and Strychnine Each Fluid ounce contains: * * * Quinine Sulphate 4 grains, Strychnine Is grains Alcohol 20%"; "Elixir Triple Bromides Each Ounce Contains Bromide Ammonia 40 Grains Bromide Potassium 40 Grains Bromide Sodium 40 Grains Prepared by P. H. Mallen Company, Chicago."

The information charged adulteration of certain of the products in that they were sold under names recognized in the National Formulary and differed from the standard of strength, quality, and purity as determined by the tests laid down in the said formulary official at the time of investigation in the following respects: The syrup of hypophosphites compound contained not more than 5.25 grams of hypophosphorous acid per 1,000 cubic centimeters, equivalent to 2.39 grains per fluid ounce, and not more than 0.88 gram anhydrous quinine and strychnine per 1,000 cubic centimeters, equivalent to 0.40 grain per fluid ounce, whereas the formulary provides that syrup of hypophosphites compound shall contain the equivalent in hypophosphorous acid of not less than 7.95 grams per 1,000 cubic centimeters, equivalent to 3.6 grains per fluid ounce, and not less than 1.06 grams of anhydrous quinine and strychnine per 1,000 cubic centimeters, equivalent to 0.48 grain per fluid ounce; the elixir iron pyrophosphites, quinine and strychnine contained not more than 0.728 gram of anhydrous qinine and strychnine per 1,000 cubic centimeters.